section of the useful beam along every direction except at the chest wall edge.

(2) The x-ray tube shall not permit exposure unless the appropriate barrier is in place to intercept the useful beam as required in paragraph (m)(1) of this section.

(3) The transmission of the useful beam through the primary protective barrier shall be limited such that the exposure 5 centimeters from any accessible surface beyond the plane of the primary protective barrier does not exceed $2.58X10^{-8}$ C/kg (0.1 mR) for each activation of the tube.

(4) Compliance for transmission shall be determined with the x-ray system operated at the minimum SID for which it is designed, at the maximum rated peak tube potential, at the maximum rated product of x-ray tube current and exposure time (mAs) for the maximum rated peak tube potential, and by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. The sensitive volume of the radiation measuring instrument shall not be positioned beyond the edge of the primary protective barrier along the chest wall side.

[58 FR 26401, May 3, 1993; 58 FR 31067, May 28, 1993, as amended at 64 FR 35927, July 2, 1999]

§ 1020.32 Fluoroscopic equipment.

The provisions of this section apply to equipment for fluoroscopy and for the recording of images through an image intensifier except computed tomography x-ray systems manufactured on or after November 29, 1984.

(a) *Primary protective barrier*—(1) *Limitation of useful beam.* The fluoroscopic imaging assembly shall be provided with a primary protective barrier which intercepts the entire cross section of the useful beam at any SID. The x-ray tube used for fluoroscopy shall not produce x-rays unless the barrier is in position to intercept the entire useful beam. The exposure rate due to transmission through the barrier with the attenuation block in the useful beam combined with radiation from the image intensifier if provided, shall not exceed 3.34×10^{-3} percent of the entrance exposure rate, at a distance of 10 centimeters from any accessible surface of the fluoroscopic imaging assembly beyond the plane of the image receptor. Radiation therapy simulation systems shall be exempt from this requirement provided the systems are intended only for remote control operation and the manufacturer sets forth instructions for assemblers with respect to control location as part of the information required in § 1020.30(g). Additionally, the manufacturer shall provide to users, pursuant to § 1020.30(h)(1)(i), precautions concerning the importance of remote control operation.

(2) *Measuring compliance.* The entrance exposure rate shall be measured in accordance with paragraph (d) of this section. The exposure rate due to transmission through the primary barrier combined with radiation from the image intensifier shall be determined by measurements averaged over an area of 100 square centimeters with no linear dimension greater than 20 centimeters. If the source is below the tabletop, the measurement shall be made with the input surface of the fluoroscopic imaging assembly positioned 30 centimeters above the tabletop. If the source is above the tabletop and the SID is variable, the measurement shall be made with the end of the beam-limiting device or spacer as close to the tabletop as it can be placed, provided that it shall not be closer than 30 centimeters. Movable grids and compression devices shall be removed from the useful beam during the measurement. For all measurements, the attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance exposure rate and between this point and the input surface of the fluoroscopic imaging assembly.

(b) *Field limitation*—(1) *Nonimage-intensified fluoroscopy.* (i) The x-ray field produced by nonimage-intensified fluoroscopic equipment shall not extend beyond the entire visible area of the image receptor. Means shall be provided for stepless adjustment of the field size. The minimum field size, at the greatest SID, shall be containable in a square of 5 centimeters by 5 centimeters.

(ii) For equipment manufactured after February 25, 1978, when the angle between the image receptor and the

beam axis of the x-ray beam is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with paragraph (b)(1)(i) of this section shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(2) *Image-intensified fluoroscopy.* (i) For image-intensified fluoroscopic equipment other than radiation therapy simulation systems, neither the length nor the width of the x-ray field in the plane of the image receptor shall exceed that of the visible area of the image receptor by more than 3 percent of the SID. The sum of the excess length and the excess width shall be no greater than 4 percent of the SID.

(ii) For rectangular x-ray fields used with circular image receptors, the error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor.

(iii) For equipment manufactured after February 25, 1978, when the angle between the image receptor and beam axis is variable, means shall be provided to indicate when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Compliance with paragraph (b)(2)(i) of this section shall be determined with the beam axis indicated to be perpendicular to the plane of the image receptor.

(iv) Means shall be provided to permit further limitation of the field. Beam-limiting devices manufactured after May 22, 1979, and incorporated in equipment with a variable SID and/or the capability of a visible area of greater than 300 square centimeters shall be provided with means for stepless adjustment of the x-ray field. Equipment with a fixed SID and the capability of a visible area of no greater than 300 square centimeters shall be provided with either stepless adjustment of the x-ray field or with a means to further limit the x-ray field size at the plane of the image receptor to 125 square centimeters or less. Stepless adjustment shall, at the greatest SID, provide continuous field sizes from the maximum obtainable to a field size containable in a square of 5 centimeters by 5 centimeters.

(3) If the fluoroscopic x-ray field size is adjusted automatically as the SID or image receptor size is changed, a capability may be provided for overriding the automatic adjustment in case of system failure. If it is so provided, a signal visible at the fluoroscopist's position shall indicate whenever the automatic field adjustment is overridden. Each such system failure override switch shall be clearly labeled as follows:

For X-ray Field Limitation System Failure

(c) *Activation of tube.* X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure. When recording serial fluoroscopic images, the operator shall be able to terminate the x-ray exposure(s) at any time, but means may be provided to permit completion of any single exposure of the series in process.

(d) *Entrance exposure rates.* For fluoroscopic equipment manufactured before May 19, 1995, the following requirements apply:

(1) *Equipment with automatic exposure rate control (AERC).* Fluoroscopic equipment that is provided with AERC shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 2.58×10^{-3} coulomb per kilogram (C/kg) per minute (10 roentgens per minute (10 R/min)) at the point where the center of the useful beam enters the patient, except:

(i) During recording of fluoroscopic images, or

(ii) When an optional high-level control is provided. When so provided, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 1.29×10^{-3} C/kg per minute (5 R/min) at the point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall

be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(2) *Equipment without AERC (manual mode).* Fluoroscopic equipment that is not provided with AERC shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 1.29×10^{-3} C/kg per minute (5 R/min) at the point where the center of the useful beam enters the patient, except:

(i) During recording of fluoroscopic images, or

(ii) When an optional high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(3) *Equipment with both an AERC mode and a manual mode.* Fluoroscopic equipment that is provided with both an AERC mode and a manual mode shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 2.58×10^{-3} C/kg per minute (10 R/min) in either mode at the point where the center of the useful beam enters the patient except:

(i) During recording of fluoroscopic images, or

(ii) When the mode or modes have an optional high-level control, in which case that mode or modes shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 1.29×10^{-3} C/kg per minute (5 R/min) at the point where the center of the useful beam enters the patient, unless the high-level control is activated. Special means of activation of high-level controls shall be required. The high-level control shall be operable only when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level is being employed.

(4) *Measuring compliance.* Compliance with paragraph (d) of this section shall be determined as follows:

(i) If the source is below the x-ray table, the exposure rate shall be measured at 1 centimeter above the tabletop or cradle.

(ii) If the source is above the x-ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(iii) In a C-arm type of fluoroscope, the exposure rate shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the imaging assembly.

(iv) In a lateral type of fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.

(5) *Exemptions.* Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in paragraph (d) of this section.

(e) *Entrance exposure rate limits.* For fluoroscopic equipment manufactured on and after May 19, 1995, the following requirements apply:

(1) Fluoroscopic equipment operable at any combination of tube potential and current that results in an exposure rate greater than 1.29×10^{-3} C/kg per minute (5 R/min) at the point where the center of the useful beam enters the patient shall be equipped with AERC. Provision for manual selection of technique factors may be provided.

(2) Fluoroscopic equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 2.58×10^{-3} C/kg per minute (10 R/min) at the point

where the center of the useful beam enters the patient except:

(i) During the recording of images from an x-ray image-intensifier tube using photographic film or a video camera when the x-ray source is operated in a pulsed mode.

(ii) When an optional high-level control is activated. When the high-level control is activated, the equipment shall not be operable at any combination of tube potential and current that will result in an exposure rate in excess of 5.16×10^{-3} C/kg per minute (20 R/min) at the point where the center of the useful beam enters the patient. Special means of activation of high-level controls shall be required. The high-level control shall only be operable when continuous manual activation is provided by the operator. A continuous signal audible to the fluoroscopist shall indicate that the high-level control is being employed.

(3) *Measuring compliance.* Compliance with paragraph (e) of this section shall be determined as follows:

(i) If the source is below the x-ray table, the exposure rate shall be measured at 1 centimeter above the tabletop or cradle.

(ii) If the source is above the x-ray table, the exposure rate shall be measured at 30 centimeters above the tabletop with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement.

(iii) In a C-arm type of fluoroscope, the exposure rate shall be measured at 30 centimeters from the input surface of the fluoroscopic imaging assembly, with the source positioned at any available SID, provided that the end of the beam-limiting device or spacer is no closer than 30 centimeters from the input surface of the fluoroscopic imaging assembly.

(iv) In a lateral type of fluoroscope, the exposure rate shall be measured at a point 15 centimeters from the centerline of the x-ray table and in the direction of the x-ray source with the end of the beam-limiting device or spacer positioned as closely as possible to the point of measurement. If the tabletop is movable, it shall be positioned as closely as possible to the lateral x-ray source, with the end of the beam-limiting device or spacer no closer than 15 centimeters to the centerline of the x-ray table.

(4) *Exemptions.* Fluoroscopic radiation therapy simulation systems are exempt from the requirements set forth in paragraph (e) of this section.

(f) *Indication of potential and current.* During fluoroscopy and cinefluorography, x-ray tube potential and current shall be continuously indicated. Deviation of x-ray tube potential and current from the indicated values shall not exceed the maximum deviation as stated by the manufacturer in accordance with §1020.30(h)(3).

(g) *Source-skin distance.* Means shall be provided to limit the source-skin distance to not less than 38 centimeters on stationary fluoroscopes and to not less than 30 centimeters on mobile and portable fluoroscopes. In addition, for image-intensified fluoroscopes intended for specific surgical application that would be prohibited at the source-skin distances specified in this paragraph, provisions may be made for operation at shorter source-skin distances but in no case less than 20 centimeters. When provided, the manufacturer must set forth precautions with respect to the optional means of spacing, in addition to other information as required in §1020.30(h).

(h) *Fluoroscopic timer.* Means shall be provided to preset the cumulative on-time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed 5 minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative on-time. Such signal shall continue to sound while x-rays are produced until the timing device is reset. As an alternative to the requirements of this paragraph, radiation therapy simulation systems may be provided with a means to indicate the total cumulative exposure time during which x-rays were produced, and which is capable of being reset between x-ray examinations.

(i) *Mobile and portable fluoroscopes.* In addition to the foregoing requirements of this section, mobile and portable

fluoroscopes shall provide intensified imaging.

[58 FR 26404, May 3, 1993, as amended at 59 FR 26404, May 19, 1994]

§ 1020.33 Computed tomography (CT) equipment.

(a) *Applicability*. (1) The provisions of this section, except for paragraphs (b), (c)(1), and (c)(2) are applicable as specified herein to CT x-ray systems manufactured or remanufactured on or after September 3, 1985.

(2) The provisions of paragraphs (b), (c)(1), and (c)(2) are applicable to CT x-ray systems manufactured or remanufactured on or after November 29, 1984.

(b) *Definitions*. As used in this section, the following definitions apply:

(1) *Computed tomography dose index (CTDI)* means the integral of the dose profile along a line perpendicular to the tomographic plane divided by the product of the nominal tomographic section thickness and the number of tomograms produced in a single scan; that is:

$$\mathrm{CTDI} = 1/\mathrm{nT}\int_{-7\mathrm{T}}^{+7\mathrm{T}} \mathrm{D(z)dz}$$

where:

z=position along a line perpendicular to the tomographic plane.
D(z)=Dose at position z.
T=Nominal tomographic section thickness.
n=Number of tomograms produced in a single scan.

This definition assumes that the dose profile is centered around z=0 and that, for a multiple tomogram system, the scan increment between adjacent scans is nT.

(2) *Contrast scale* means the change in linear attenuation coefficient per CT number relative to water; that is:

$$\mathrm{Contrast\,scale} = \frac{\mu_x - \mu_w}{(\mathrm{CT})_x - (\mathrm{CT})_w}$$

where:

μ_w=Linear attenuation coefficient of water.
μ_x=Linear attenuation coefficient of material of interest.
$(CT)_w$=CT number of water.
$(CT)_x$=CT number of material of interest.

(3) *CT conditions of operation* means all selectable parameters governing the operation of a CT x-ray system including nominal tomographic section thickness, filtration, and the technique factors as defined in §1020.30(b)(36).

(4) *CT number* means the number used to represent the x-ray attenuation associated with each elemental area of the CT image.

(5) [Reserved]

(6) *CT dosimetry phantom* means the phantom used for determination of the dose delivered by a CT x-ray system. The phantom shall be a right circular cylinder of polymethl-methacrylate of density 1.19±0.01 grams per cubic centimeter. The phantom shall be at least 14 centimeters in length and shall have diameters of 32.0 centimeters for testing any CT system designed to image any section of the body (whole body scanners) and 16.0 centimeters for any system designed to image the head (head scanners) or for any whole body scanner operated in the head scanning mode. The phantom shall provide means for the placement of a dosimeter(s) along its axis of rotation and along a line parallel to the axis of rotation 1.0 centimeter from the outer surface and within the phantom. Means for the placement of a dosimeter(s) or alignment device at other locations may be provided for convenience. The means used for placement of a dosimeter(s) (i.e., hole size) and the type of dosimeter(s) used is at the discretion of the manufacturer. Any effect on the doses measured due to the removal of phantom material to accommodate dosimeters shall be accounted for through appropriate corrections to the reported data or included in the statement of maximum deviation for the values obtained using the phantom.

(7) *Dose profile* means the dose as a function of position along a line.

(8) *Modulation transfer function* means the modulus of the Fourier transform of the impulse response of the system.

(9) *Multiple tomogram system* means a CT x-ray system which obtains x-ray transmission data simultaneously during a single scan to produce more than one tomogram.

(10) *Noise* means the standard deviation of the fluctuations in CT number expressed as a percent of the attenuation coefficient of water. Its estimate